K113628

JUN 12 2012

510(k) Summary
(As required by section 21 CFR 807.92(c))

Contact:	Catheter Robotics, Inc. Jennifer Englund Vice President, Clinical Affairs and Regulatory Telephone: 973-691-2000 / Fax: 973-810-4887 Email: jenglund@catheterrobotics.com
Date Prepared:	December 6, 2011
Product Trade Name:	Amigo Remote Catheter System (RCS) & Accessories, Model 1012
Common/Usual Name:	Steerable Catheter Control System
Classification Name:	System, Catheter Control, Steerable, Class II (21 CFR 870.1290, Product Code DXX)
Predicate Devices:	Hansen Medical Catheter Control System (CCS) & Accessories, Hansen Medical, Inc. (K052480) Stereotaxis Niobe MNS Catheter Control System & Accessories, Stereotaxis, Inc. (K021555)
Manufacturer:	Catheter Robotics, Inc. 500 International Drive Mount Olive, NJ 07828
Establishment Registration:	3008365050

Device Description:

The Amigo RCS is designed to create a simple interface with commercially available catheters allowing the physician to insert, withdraw and rotate the catheter, and deflect the catheter tip via the remote controller. Catheter placement and positioning is performed under direct visualization using standard imaging equipment, while enabling the physician to remain seated and away from the x-ray radiation field. The Amigo RCS system includes several disposable components which help to maintain the sterile field.

Statement of Intended Use:

The Amigo Remote Catheter System (RCS) is intended to facilitate manipulation, positioning and control of percutaneous diagnostic catheters for stimulating cardiac tissue and for recording electrophysiological data in the right atrium and right ventricle.

The safety and effectiveness of this device for ablation in the treatment of cardiac arrhythmias including atrial fibrillation, has not been established.

The safety and effectiveness of this device for cardiac mapping when used with any catheter other than the Boston Scientific Blazer™ Dx-20 has not been established.

Summary of Technological Characteristics in Comparison to the Predicate Device:

The Amigo RCS is substantially equivalent to the predicated devices. Both the proposed and predicate devices provide stability for positioning of EP catheters, while allowing the physician to perform the procedure from a position beyond the radiation field.

Substantial Equivalence:

Based upon the intended use and technical information provided in this pre-market notification, the Amigo RCS and accessories have been shown to be substantially equivalent to currently marketed predicate devices.

Summary of Non-Clinical Testing:

Design verification and validation testing was performed to ensure that the Amigo RCS and accessories met design specifications and customer requirements. Testing activities included electrical/mechanical safety tests and functional performance tests as well as cleaning, biocompatibility, sterilization, shelf life and transit studies.

Risk analysis activities were completed based on ISO 14971. Electrical/mechanical device safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1 and 60601-1-2, respectively. Supporting biocompatibility studies were performed in accordance with ISO 10993-1.

Summary of Clinical Testing:

The clinical evaluation confirmed that Amigo RCS is safe and effective and operates as designed for its intended use and as described in its proposed labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 12 2012

Catheter Robotics Inc.
c/o Ms. Jennifer Englund
Vice President-Clinical and Regulatory Affairs
500 International Drive, Suite 120
Mount Olive, NJ 07828

Re: K113628
Trade Name: Amigo Remote Catheter System & Accessories, Model 1012
Regulatory Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II (Two)
Product Code: DXX
Dated: May 31, 2011
Received: June 4, 2011

Dear Ms. Englund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K113628_____

Device Name: **Catheter Robotics, Inc.**
Amigo Remote Catheter System (RCS) & Accessories,
Model 1012

Indications for Use:

The Amigo Remote Catheter System (RCS) is intended to facilitate manipulation, positioning and control of percutaneous diagnostic catheters for stimulating cardiac tissue and for recording electrophysiological data in the right atrium and right ventricle.

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The safety and effectiveness of this device for cardiac mapping when used with any catheter other than the Boston Scientific Blazer™ Dx-20 has not been established.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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